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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/821,734	03/30/2001	Artur Pedyczak	API-02-07-US	5460

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EXAMINER

HUFF, SHEELA JITENDRA

ART UNIT	PAPER NUMBER
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1643

DATE MAILED: 01/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/821,734

Applicant(s)

PEDYCZAK ET AL.

Examiner

Sheela J. Huff

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 December 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-9,30,31 and 33-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 7 and 34 is/are allowed.
- 6) ☒ Claim(s) 6,8,9,30,31,33 and 35-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

The amendment filed on 12/1/05 has been considered. Applicant's arguments are deemed to be persuasive-in-part.

Claims 6-9, 30-31 and 33-41 are pending.

All of the rejections have been withdrawn. Two of the rejections under 35 U.S.C. 112, first paragraph, have been withdrawn in order to be re-written in view of the amended claims.

Response to Arguments

Declaration

The declaration remains defective for the reasons of record. Applicant did not address this issue.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

Claims 35-36 and 40-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in

the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims read on a nucleic acid sequence that is complementary to SEQ ID NO. 12, 14-17 or nucleic acid sequences that hybridize to SEQ ID NO. 12, 14-17 encoding PSMA derived peptide.

Sequences that are complementary to or hybridize to SEQ ID NO. 12-17 are the antisense strand and the antisense strand usually does not encode any peptide and certainly does not encode the same sequence that the sense strand encodes.

Applicant has not provided any examples to show that the antisense strand can encode any peptide or even encode the PSMA derived peptides. In view of the fact that the antisense strand does not encode a peptide and in view of the lack of examples to that the antisense strand encodes a peptide, it is the Examiner's position that the undue experimentation would be required by one skilled in the art to make the instant invention.

Response to applicant's arguments

Applicant argues that they are entitled to the large number of sequences in view of *In re Wallach*. This does not address the rejection. The rejection is based on the fact that antisense strands do not encode peptides.

Claims 6, 8-9, 30-31 and 33 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid sequence encoding SEQ ID NO. 12-17, does not reasonably provide enablement for a nucleic acid

sequence encoding SEQ ID NO. 12-17 with conservative substitutions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicant claims and discloses a nucleic acid sequence encoding SEQ ID NO. 12-17 with conservative substitutions (being defined on page 7 of the specification).

Protein chemistry is probably one of the most unpredictable areas of biotechnology. For example, Jackman et al Biochem. J. vol. 282 p. 915 (1992) shows that a single conservative amino acid substitution in tyrosinase results in the stabilization of the oxy form of the tyrosinase. McLane et al Biochemistry vol. 33 p. 2576 (1994) discloses that conservative substitutions in alpha Bungarotoxin result in a variety of effects (ranging from minor effects on activity to abolishing the activity) (see abstract). Ding et al J. Exp. Med. Vol 191 p. 213 (2000) discloses that replacing isoleucine with alanine abrogates the immunostimulatory activity of the protein.

1. These references demonstrate that even a single amino acid substitution or what appears to be an inconsequential chemical modification, will often dramatically affect the biological activity of the protein.

2. Although biotechnology has made great strides in the recent past, these references serve to demonstrate exactly how little we really know about the art. Elucidation of the genetic code induces one to believe that one can readily obtain a functional synthetic protein for any known nucleic acid sequence with predictable results. The results of the construction of synthetic proteins remain very unpredictable as Burgess et al, Lazar et al, Schwartz et al, Lin et al and Acland et al conclusively demonstrate.

3. In view of the lack of guidance, lack of examples, and lack of predictability associated with regard to producing and using the myriad of derivatives encompassed

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in the scope of the claims, one skilled in the art would be forced into undue experimentation in order to practice the broadly claimed invention.

Claims 8, 31 and 37-39 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to polypeptides (1) having at least 85% identity with SEQ ID no. 13 and (2) having identity to SEQ ID NO. 12 and 14-17. While the sequences of SEQ ID NO:12-17 are adequately described in the specification as-filed, thereby providing an adequate basis for the polypeptides of SEQ ID NO:12-17; there is insufficient written description as to the identity of a sequence having at least 85% sequence identity to SEQ ID NO:13 and having identity to SEQ ID NO. 12 and 14-17 that would still maintain the function of the encoded polypeptide. Consequently, the specification does not provide an adequate written description of a nucleic acid sequence encoding a PSMA derived peptide having at least 85% sequence identity to SEQ ID NO:13 or having identity to SEQ ID NO. 12 and 14-17.

The specification as filed does not provide adequate written description support for a nucleic acid sequence encoding a PSMA derived peptide having at least 85% sequence identity to SEQ ID NO:13 or having identity to SEQ ID NO. 12 and 14-17. Polypeptides having diverse functions are encompassed by the phrase at least 85% identity and "having identity". Thus a broad genus having potentially highly diverse functions is encompassed by the phrases and conception cannot be achieved until

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reduction to practice has occurred, regardless of the complexity or simplicity of the method. For example, Skolnick et al. (Trends in Biotech., 18(1):34-39, (2000) teach that the skilled artisan is well aware that assigning functional activities for any particular protein or protein family based upon sequence homology is inaccurate, in part because of the multifunctional nature of proteins (e.g., Abstract and Sequence-based approaches to function prediction, page 34). Even in situations where there is some confidence of a similar overall structure between two proteins, only experimental research can confirm the artisan's best guess as to the function of the structurally related protein (see in particular Abstract and Box 2). Adequate written description requires more than a mere statement that it is part of the invention. The sequence itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.

Therefore, only SEQ ID No. 12-17 meet the written description provision of 35 U.S.C. 112, first paragraph. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed. (See page 1117.) The specification does not clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed. (See Vas-Cath at page 1116.). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, & 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Applicant is invited to point to clear support or specific examples of the claimed invention in the specification as-filed.

Claims 31 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 39 is directed to an expression vector comprising a nucleic acid molecule of claim 37. This is the same as claim 8. It is confusing as to why applicant has two claims dependent claiming an expression vector dependent on claim 37.

Claim 31 uses the terminology "having identity". It is not clear how much identity is needed.

Allowable Subject Matter

Claims 7 and 34 remain allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheela J. Huff whose telephone number is 571-272-0834. The examiner can normally be reached on Tuesdays and Thursdays from 5:30am to 2:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Sheela J Huff
Primary Examiner
Art Unit 1643

sjh